COVER PAGE

Official Title of the Study: POSToperative PAcing for Cardiac Efficiency (POSTPACE)

NCT number: NCT ID not yet assigned

Date of the Document: 09/17/2026

Ann & Robert H. Lurie Children's Hospital of Chicago

R S C H

Affix Patient Label Here
Note: Label required for cover page, but is optional for other pages if the following information is provided:
Patient Name:
MRN:

Parent Permission for a Child to Take Part in a Research Study

Study Name: POSToperative **PA**cing for **C**ardiac **E**fficiency (POSTPACE)
Sponsored by: The Graeme McDaniel Foundation
Name of Researcher (referred to as the study doctor): Dr. Gregory Webster

This form asks permission for your child to join a research study at Ann & Robert H. Lurie Children's Hospital of Chicago ("Lurie Children's"). Research helps doctors improve patient care. Taking part is your choice. You may say yes or no. Your decision will not affect your child's regular care. Please read this form and ask any questions. You may also talk with family members or your child's healthcare providers before deciding.

What are the purpose and goals of this study?

After heart surgery, doctors may use temporary pacemaker wires to control a child's heart rate. These wires are placed during surgery as part of normal care. Doctors use different pacing settings, and we do not know which works best. This study will compare settings already used in regular care. The results may help improve care for children after heart surgery. We expect about 46 children to be part of this study.

If I agree to allow my child to take part in this study, what would they need to do?

- Study staff will review your child's medical record.
- The study will use temporary pacing wires placed during surgery for normal care. No extra wires or devices will be added.
- During the first few hours after surgery, your child will receive commonly used pacing settings. The order will be chosen by chance.
- The study team will collect information from monitors already used in the Cardiac Intensive Care Unit (CICU), including heart rate, blood pressure, and oxygen levels.
- Some information will also be collected on the second and third days after surgery.
- The team will review laboratory results, medicines, surgery details, and recovery information.
- Your child will not have extra blood tests, scans, procedures, or monitors for this study.
- Your child's doctors may change or stop the study procedures if needed for your child's safety.

What are the risks, side effects, or discomforts related to the study?

Pacing could rarely cause an abnormal heartbeat, a change in blood pressure, a change in the heart's rhythm, and other changes in the heart's function. These problems can usually be corrected by changing or stopping the pacing and they are the same changes that can occur when a doctor paces the heart outside a research study. Your child will be closely monitored by the medical team. There is also a small risk that someone could see your child's private information. We will take every step to protect it.

What are the benefits from this study?

Your child may not directly benefit. The pacing settings are already used in normal care. Your child's doctors may learn which setting works best for your child, but this may not happen. The study may help improve care for future children after heart surgery.

What other options does my child have?
Your child does not have to join this study. Saying no or leaving the study will not affect your child's medical care.

What if my child's doctor or I do not think they should stay in the study?

You may stop your child's participation at any time. Your child's doctors may also stop the study procedures if they believe it is best for your child.

Returning Study Results:

The study team will not provide individual research results. The study does not include extra tests or genetic testing. It uses information collected during normal care.

Important New Information:

We will tell you if we learn new information that may make you change your mind about allowing your child to be in this study.

Planned Sharing of Your Child's Information:

The information that may be collected and shared will include your child's:

- Personal and health information
- Past and present medical records
- Records from study visits and phone calls

By allowing your child to join, you give permission to use and share this information until the study is complete.

The study staff, employees, and Medical Staff of Lurie Children's may use your child's information for this study and share it with:

- The study sponsor, The Graeme McDaniel Foundation, and those working with the sponsor.
- The Institutional Review Board (the committee that is in charge of protecting the rights of all adults and children who take part in research studies).
- Colleagues at other academic sites that join our network and sign data use agreements to protect research information.
- Your child's other providers and their staff involved in your child's care, if their provider is a part of the Lurie Children's electronic health information exchange.
- The Office of Human Research Protections (OHRP), the Food and Drug Administration (FDA), or other government offices.

These are the only people we will share your child's information with. We cannot guarantee that those listed above will not share it with others without your permission.

Your child's name will not be included in any written or verbal reports of study results.

What if I decide not to give permission to use and give out my child's information?

Your child cannot join the study unless you give permission to use their information. You may later withdraw permission by writing to the study doctor. The study team may still use information collected before receiving your request.

Can I review or copy my child's information?

You cannot review the study's research records. Information related to your child's medical care will be placed in the medical record. You may still request a copy of that medical record.

Will my child's information or samples be used in future research studies?

No samples will be stored for future research. Study data without identifying information may be used in future research to improve care after surgery.

Will my child's samples be used for commercial purposes?

No samples are collected for this study. Samples collected for medical care will not be stored or used for commercial purposes.

Costs Related to this Study:

The study sponsor will pay for all study related costs. The cost of the surgery and the recovery period will remain billable to you or your insurance, and participation in this study will not decrease those costs.

Payment for Taking Part in this Study:

You will be paid $100 for your child taking part in this study (as a digital gift card).

Your Child's Rights When Taking Part in this Study:

Allowing your child to join does not give up any legal rights. You may stop your child's participation at any time. Your decision will not affect your child's regular care.

Who can answer my questions about this study?

If you have any questions, contact the study doctor, Gregory Webster, MD, MPH at 312-227-4397, during a workday or 312-227-4000 at night or on weekends.

If you have questions about your child's rights or if you have a complaint, you can call the IRB Office at (312) 503-7110; or via email at IRB@luriechildrens.org.

You will be given a copy of this consent form.

Signatures:

Printed Name of Child:

Parent/LAR Signature:

By signing this form, I affirm: 1) I have read this form. 2) The research has been explained to me. 3) All of my questions have been answered. I give my consent for my child to take part in this research study.	
Signature of Parent or Legally Authorized Representative (LAR):	Date:
Printed Full Name:	
Relationship to Child:	

Second Parent/LAR Signature:

Note: The IRB has determined that the signature of a second parent (unless the second parent is deceased, unknown, or not reasonably available, or when only one parent has legal responsibility) is needed for this study.	
By signing this form, I affirm: 1) I have read this form. 2) The research has been explained to me. 3) All of my questions have been answered. I give my consent for my child to take part in this research study. 4) I give my consent my child for my child to take part in this research study.	
Signature of 2nd Parent or Legally Authorized Representative (LAR):	Date:
Printed Full Name:	

Signature of Authorized Person Obtaining Consent:

I certify that I have explained the above to the parent(s)/LAR and the signature(s) was obtained voluntarily.	
Signature:	Date:
Printed Full Name:	

Signature of Interpreter/Witness*:

☐ Not applicable, no interpreter used.
I attest that the study information has been presented to the parent/legally authorized representative (LAR) in their native language. They were given the opportunity to have all questions answered.
Signature of Interpreter/Witness:
Printed Full Name or Unique Phone ID/Company Name:

Note to Investigators: When obtaining consent from a non-English speaking parent/LAR

When a study-specific translated consent document is not available, a translated "short form" (available in several languages on the IRB website) may be used, in combination with a verbal presentation of study information (as outlined in this English consent) with the aid of an interpreter.

a. *The consent process must be witnessed by an individual who is fluent in both English and the language understandable the subject. The interpreter may serve as the witness and should sign both the English consent document and short form.*

b. *The parent/LAR should sign the short form (in the language they understand).*

c. *The investigator and/or study staff authorized by the IRB to obtain consent must sign the approved English version of the consent form.*

d. *A copy of both the IRB-approved English consent form (i.e., the summary) and the translated version of the short form must be given to the parent/LAR.*